MAERSK MEDICAL

510(K) SUMMARY

1.0 Sponsor

Maersk Medical, Ltd.
Thornhill Road, North Moons Moat
Redditch, Worcestershire, England
Registration Number: 8010113

2.0 Submission Correspondent

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Contact Name: Lara N. Simmons
Contact Title: Corporate Director, Regulatory Affairs
Phone: 847-949-2639
Fax: 847-837-2787
Email: Lsimmons@Medline.com

3.0 Regulatory Information

Device Name: Hydrophilic Wound Dressing
Proprietary Name: Arglaes-AB Powder Dressing
Common Name: Powder Wound Dressing
Device Code: 79 MGP
Device Classification: II

4.0 Substantial Equivalence

Arglaes-AB ™ Powder is substantially equivalent in form and content to the Arglaes-AB ™ Antimicrobial Film (K970566, K990810) and Island (K973657, K990810) dressings and the Sorbsan (K881854, K914575). It is similar in function to the Silverlon Wound Packing Strips (K984210).

5.0 Device Description

Arglaes-AB Powder is a dressing in powder form that is comprised of silver oxide stabilized within a polymer composed of phosphorus oxide, sodium oxide, calcium oxide and silver oxide. The balance of the powder is comprised of phosphorus oxide, sodium oxide and calcium oxide (no silver) and of sodium alginate powder.

Sodium alginate is substantially equivalent to the alginate component of the Arglaes-AB Antimicrobial Barrier Island Dressing. Its primary function is to absorb wound exudate and to help control minor bleeding.

The silver oxide is substantially equivalent to the silver oxide component of the Arglaes-AB Antimicrobial Barrier Film and Island dressings. This helps resist bacterial penetration through the dressing.[3]

6.0 Intended Use

A topical wound for the treatment of difficult to dress wounds, surface wounds, exudating wounds, including:

- pressure ulcers,
- venous ulcers
- diabetic ulcers
- arterial ulcers
- donor sites
- dermal lesions
- trauma injuries
- incisions

Laboratory studies for Arglaes AB wound powder have shown the product to resist bacterial penetration through the dressing which may help minimize the risk of infection[4]. This effect may be limited based upon evenness of application and contact with the wound surface.

7.0 Technological Characteristics

There are no major differences in technical characteristics between this product and the predicate devices. The only difference is this is a powder form of the already marketed Arglaes-AB™ Film and Arglaes-AB™ Island dressings.

[3] This effect has not been demonstrated clinically at this time
[4] This effect has not been demonstrated clinically at this time

8.0 Substantial Equivalence

This product was tested using the **USP XXIII Preservative Test** and the **7 – day Antimicrobial Barrier (Strike Through) Test.** Testing was conducted on the following organisms:

USP XXIII Preservative Test:

Similar to the Arglaes-AB™ Antimicrobial Film Dressing, a USP XXIII Preservative Test and a Microbial Barrier (Strike-Through) study were performed on the Arglaes™ Powder. These studies indicate that the Arglaes™ Powder does resist bacterial penetration through the dressing by the listed organisms.

Aspergillus niger
Candida albicans
Pseudomonas aeruginosa
Staphylococcus aureus
Escherichia coli

7-Day Antimicrobial Barrier (Strike Through) Test

Aspergillus niger **(ATCC #16404)**
Bacillus Subtilis **(ATCC #9372)**
Candida Albicans **(ATCC #10231)**
Enterobacter cloacae **(ATCC #13047)**
Enterococcus faecalis **(vancomycin-resistant, ATCC #51575)**
Enterococcus faecium **(ATCC #19434)**
Escherichia coli **(ATCC #8739)**
Klebsiella pneumoniae **(ATCC#13883)**
Proteus mirabilis **(ATCC #12453)**
Proteus vulgaris **(ATCC #13315)**
Serratia marcescens **(ATCC #14756)**
Staphylococcus aureus **(methicillin- and gentamicin- resistant ATCC #33593)**
Staphylococcus aureus **(ATCC #6538)**
Staphylococcus aureus **(methicillin resistant ATCC #33591)**
Staphylococcus epidermidis **(ATCC #12228)**
Streptococcus agalactiae **(ATCC #13813)**
Streptococcus pyogenes **(ATCC #8669)**

Arglaes-AB ™ Powder was tested for its ability to prevent bacterial strikethrough for a 7 day period. The product met all requirements for the above reference test, demonstrating that it effectively resists bacterial penetration through the dressing for a 7 day period *in vitro*.

9.0 Biocompatibility

This product was tested in accordance with ISO 10993 requirements for biocompatibility using the following tests:

Cytotoxicity
Primary Skin Irritation
Dermal Sensitization

The product was not found to be either an irritant or a sensitizer and all test results were acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Maersk Medical, Ltd.
c/o Ms. Lara N. Simmons
Corporate Director, Regulatory Affairs
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060

Re: K004028
Trade Name: Arglaes AB Powder Dressing
Regulatory Class: II
Product Code: MGP
Dated: December 26, 2000
Received: December 27, 2000

Dear Ms. Simmons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAERSK MEDICAL

2.0 Indications for Use

510(k) Number (if known): K004028

Device Name: Arglaes AB Wound Powder

Indications For Use:

A topical wound dressing for the treatment of difficult to dress wounds, surface wounds, exudating wounds, including:

- pressure ulcers,
- venous ulcers
- diabetic ulcers
- arterial ulcers
- donor sites
- dermal lesions
- trauma injuries
- incisions

Laboratory studies for Arglaes AB wound powder have shown the product to resist bacterial penetration through the dressing which may help minimize the risk of infection[1]. This effect may be limited based upon evenness of application and contact with the wound surface.

[1]This effect has not been demonstrated clinically at this time.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurol[illegible] Devices

03/20/01

510(k) Number K004028